#1 reclude

2. (Amended) A composition as claimed in claim 1, including said one or more non-hygroscopic additives, said one or more non-hygroscopic additives comprising a carrier that comprises either

(a) particles having a diameter of less than 10 microns or equal to about 10 microns, such that at least 50% of said composition consists of primary particles having a diameter of less than 10 microns or equal to about 10 microns; or

(b) coarse particles having a diameter of at least 20 microns, such that an ordered mixture is formed between (i) the carrier and (ii) the polypeptide of (A) and the one or more surfactant compounds of (B).

#2

12. (Amended) The composition of claim 1, wherein at least one of said one or more surfactant compounds is a bile salt, an alkyl glycoside, a cyclodextrin or derivative thereof, a single-chain phospholipid, or a double-chain phospholipid in which each chain of the double-chain phospholipid is eight or fewer carbon atoms in length.

#3 12

21. (Amended) A method for systemic administration of a biologically active polypeptide, comprising

providing a composition comprising a mixture of active compounds (A) a biologically active polypeptide, and (B) an enhancer compound which (i) has a consistency that permits it to be processed into primary particles having a diameter less than 10 microns, and (ii) enhances the systemic absorption of the polypeptide in the lower respiratory tract of a patient, said composition being in the form of a dry powder suitable for inhalation from a dry powder inhaler device; and

causing said patient to inhale through the mouth said composition from a dry powder inhaler device; provided that at least 50% of the total mass of the active compounds, at the point the active compounds enter the respiratory tract of the patient, consists of particles having a diameter less than 10 microns or equal to about 10 microns.

#4

31. (Amended) The composition of claim 1, wherein at least one of said one or more surfactant compounds is a bile salt.

61. (Amended) A composition comprising a mixture of active compounds (A) a biologically active polypeptide, and (B) an enhancer compound that (i) has a consistency that permits it to be processed into primary particles having a diameter less than 10 microns, and (ii) enhances the systemic absorption of said polypeptide in the lower respiratory tract of a patient, said composition being in the form of a dry powder suitable for inhalation from a dry powder inhaler device, wherein at least 50% of the total mass of active compounds consists of primary particles having a diameter less than 10 microns or equal to about 10 microns, said primary particles optionally being formed into agglomerates; and

a carrier comprising particles having a diameter of at least 20 microns, such that an ordered mixture is formed between the active compounds and the carrier.

78. (Amended) A dry powder inhaler device containing a composition comprising a mixture of active compounds (A) a biologically active polypeptide, and (B) an enhancer compound which (i) has a consistency that permits it to be processed into primary particles having a diameter less than 10 microns, and (ii) enhances the systemic absorption of said polypeptide in the lower respiratory tract of a patient, said composition being in the form of a dry powder suitable for inhalation from a dry powder inhaler device, wherein at least 50% of the total mass of active compounds consists of primary particles having a diameter less than 10 microns or equal to about 10 microns, said primary particles optionally being formed into agglomerates; the dry powder inhaler device being adapted for inhalation through the mouth.

79. (Amended) The dry powder inhaler device of claim 78, wherein the composition comprises a carrier, which comprises either

(a) particles having a diameter of less than 10 microns or equal to about 10 microns, such that at least 50% of said composition consists of optionally agglomerated primary particles having a diameter of less than 10 microns or equal to about 10 microns; or

(b) particles having a diameter of at least 20 microns, such that an ordered mixture is formed between the active compounds and the carrier.

96. The dry powder inhaler device of claim 78, wherein said composition is in the form of said agglomerates, said device being configured to induce the majority of said agglomerates to break down into particles having a diameter less than 10 microns or equal to about 10 microns, upon inhalation of said agglomerates from said device.

102. (Amended) A propellant-free composition consisting of

(A) a polypeptide;

(B) a surfactant compound that (i) has a consistency that permits it to be processed into primary particles having a diameter less than 10 microns, and (ii) enhances the systemic absorption of said polypeptide in the lower respiratory tract of a patient; and,

(C) one or more additives selected from the group consisting of a mono- or disaccharide, raffinose, melezitose, sugar alcohol and polyol, said composition being in the form of a dry powder suitable for inhalation from a dry powder inhaler device and into the lower respiratory tract, wherein at least 50% of the total mass of (A) and (B) consists of primary particles having a diameter less than 10 microns or equal to about 10 microns, and wherein the surfactant compound is selected from the group consisting of a salt of a fatty acid, bile salt, single-chain phospholipid, double-chain phospholipid in which each chain of the double-chain phospholipid is eight or fewer carbon atoms in length, alkyl glycoside, cyclodextrin or derivative thereof, salt of a glycyrrhizine acid, salt of a saponin glycoside, salt of an acyl carnitine, and sodium salicylate.

103. (Amended) The composition of claim 102, wherein the one or more additives comprise either

(a) particles having a diameter of less than 10 microns or equal to about 10 microns, such that at least 50% of the composition consists of primary particles having a diameter of less than 10 microns or equal to about 10 microns; or

(b) coarse particles having a diameter of at least 20 microns, such that an ordered mixture is formed between (i) the one or more additives, and (ii) the polypeptide of (A) and the surfactant compound of (B).

#9 112. (Amended) The composition of claim 102, wherein the surfactant compound is a bile salt, an alkyl glycoside, a cyclodextrin or derivative thereof, a single-chain phospholipid, or a double-chain phospholipid in which each chain of the double-chain phospholipid is eight or fewer carbon atoms in length.

#10 117. (Amended) The composition of claim 102, wherein the surfactant compound is a bile salt.--

Please add claim 119.

#11 -- 119. The composition of claim 102, wherein the one or more additives are selected from the group consisting of lactose, glucose, raffinose, melezitose, lactitol, maltitol, trehalose, sucrose, and mannitol.--